

REMARKS

In the Office Action dated December 10, 2004, claims 1-17 are pending. Claims 1-8 and 13-17 are under examination; and claims 9-12 have been withdrawn from further consideration. Claims 8 and 13 are allowed. Claims 1-2 and 14-17 are rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enabling support in the specification. Claims 1-7 and 14-17 are rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. Claims 1-6 and 14-17 are rejected under 35 U.S.C. §102(a) as allegedly anticipated by U.S. Published Application 2002/0169299 ("the '299 application"), filed by Slaugenhaupt et al. The Examiner has also objected to the specification and the claims for certain alleged informalities.

This Response addresses each of the Examiner's rejections and objections. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

The specification is objected to for failing to include a reference to the priority document. In response, Applicants have amended the specification to include a reference to the priority document, U.S. Provisional Application No. 60/262,284, filed on January 17, 2001. The objection to the specification is therefore obviated and withdrawal thereof is respectfully requested.

In the claims, Applicants have canceled claims 9-12, which have been withdrawn from consideration. Applicants reserve the right to pursue the subject matter of the canceled claims in a divisional application.

Claims 14-17 are objected to, because the Examiner contends that the recitation of "isolated of RNA" in claim 14 should be "isolating RNA". Applicants have amended claim 14 as the Examiner has suggested. Thus, withdrawal of the objection to claims 14-17 is respectfully requested.

Claims 1-2 and 14-17 are rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enabling support in the specification.

The Examiner alleges that the specification does not support the full scope of the claimed methods. Specifically, the Examiner states that claims 1-2 are broadly drawn to detection of any mutations in the IKAP gene without defining the location or nature of the mutation. The Examiner also states that claims 14-17 do not specify any particular gene which contains the stated mutations. However, the Examiner has acknowledged that the specification is enabling for a method of detecting the presence of a T to C change at position 6 of the donor splice site of intron 20 of the gene encoding IKAP, as well as for a method of detecting the presence of a G to C transversion of nucleotide 2390 in exon 19 of the gene encoding IKAP.

Applicants respectfully disagree with the Examiner. Applicants respectfully submit that the specification provides adequate guidance for those skilled in the art to practice the claimed methods without undue experimentation. However, in an effort to favorably advance prosecution of the present application, Applicants have canceled claims 1-2 and have rewritten claims 3-4 as independent claims. Applicants have also amended claim 14 to specify that the mutation is in the gene encoding IKAP. Applicants respectfully submit that the claims, as amended, are fully enabled. As such, the rejection under 35 U.S.C. §112, first paragraph, is overcome. Withdrawal of the rejection is therefore respectfully requested.

Claims 1-7 and 14-17 are rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite.

The Examiner contends that claims 1-7 are indefinite for not reciting a nexus between the preamble and the method step. It is respectfully submitted that the claims have been

amended to include a recitation which clarifies the nexus between the preamble and the method step.

The Examiner has also rejected claims 4-6 for allegedly failing to identify a reference point for determining the location of "nucleotide 2390 in exon 19". In this regard, the Examiner indicates that the numbering of the IKAP cDNA varies in the prior art due to the presence of two distinct IKAP mRNA transcripts.

Applicants respectfully direct the Examiner's attention to page 3, last paragraph of the specification, where it is clearly described that the change at nucleotide 2390 in exon 19 results in a change in the corresponding amino acid at position 696. Figure 3A of the present application further illustrates nucleotide 2390 in exon 19 of the IKAP gene corresponds to the middle nucleotide of the codon for Arg (i.e., Arg at position 696). In light of the specification, the location of "nucleotide 2390 in exon 19" of the IKAP gene is clear to those skilled in the art.

Further, the Examiner has rejected claims 14-17 for failing to identify the gene containing the specified mutations. In response, Applicants have amended independent claim 14 to clarify the gene as the IKAP-encoding gene.

In view of the foregoing, it is respectfully submitted that the present claims are not indefinite. Withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is therefore respectfully requested.

Claims 1-6 and 14-17 are rejected under 35 U.S.C. § 102(a) as allegedly anticipated by U.S. Published Application 2002/0169299 ("the '299 application"), filed by Slaughaupt et al.

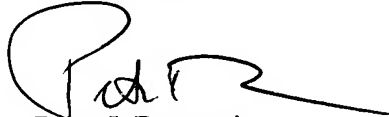
It is observed that the '299 application was published on November 14, 2002, i.e., after the filing date of the present application (January 16, 2002). The '299 application was filed on January 7, 2002, claiming priority from a provisional application filed on January 6, 2001

(i.e., before the priority date of the present application, January 17, 2001). Under these circumstances, it is believed that the rejection based on the '299 application should have been raised under §102(e), not §102(a).

In any event, Applicants respectfully submit that the '299 application is obviated because the presently claimed invention was conceived and reduced to practice prior to January 6, 2001. In this regard, Applicants provide herewith a Declaration under 37 C.F.R. §1.131, signed by both inventors of the present application (**Exhibit A**). The Declaration provides evidence that clearly establishes an invention date prior to January 6, 2001. Therefore, the rejection based on the '299 application is overcome. Withdrawal of the rejection is therefore respectfully requested.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Peter I. Bernstein', with a large, stylized initial 'P'.

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Encl.: Exhibit A (with attached Exhibits 1-4)